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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,526	06/09/2006	Masafumi Koide	8076-1004	1052

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EXAMINER
LAM, ANN Y

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,526	KOIDE, MASAFUMI	
	Examiner	Art Unit	
	ANN Y. LAM	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 3 is objected to because of the following informalities: a period is needed at the end of the sentence. Appropriate correction is required.

Claim 7 is objected to because of the following informalities: "being" in line 9 should be deleted. Appropriate correction is required.

Claim 15 is objected to because of the following informalities: the acronyms are not spelled out in the specification so it is not clear what they symbolize. (That is, these acronyms should be spelled out somewhere in the specification/claims: GOT, GPT, LDH, CPK, ALP, LAP, BUN, CRE, CH-E, LDL, CRP, TSH, GH, LH, FSH, ADH, ACTH, ANP, BNP, PSA, CEA and AFP. While acronyms are widely used and some of these are well known in the art, providing the full names somewhere in the specification/claims would make it more clear and avoid confusion since acronyms are so widely used and some may be used by those in the art to stand for different things.) Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "biological chip assemblage" in line 9. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation "biological chip assemblage" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 4-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Wigstrom et al. 20040181343.

Applicant's claim 1 recites a biological chip comprising a substrate; and a probe as a biologic material or artificial biologic material immobilized on a surface of the substrate, wherein the substrate is in the form of a column or cylinder, and wherein the probe

comprises nucleic acids, peptides or cells, and wherein the probe is immobilized on a circumferential side wall of the substrate.

Wigstrom et al. disclose these elements. Specifically, Wigstrom et al. disclose that a microfluidic chip typically comprises a plurality of microchannels through which picoliter-to-nanoliter volumes of solvent, sample, and reagents solutions progress through narrow tunnels to be mixed, separated, and/or analyzed. See paragraph 94. Wigstrom et al. also disclose that a “microfluidic substrate”, which refers to a substrate that comprises at least one microchannel, can be planar, but may be of any shape, including circular. The substrate may also have interconnecting element(s) for interfacing the microfluidic substrate with a macroscale component. See paragraph 68. Wigstrom et al. further disclose a "sensor chamber" which receives sensors and comprise outlets in one or more walls from at least two microchannels. The sensor chamber can for example be cylindrical (e.g., when the chamber is disc-shaped). One or more wall(s) and/or base can be optically transmissive. See paragraph 69. The "sensors" comprise molecules immobilized on a substrate, wherein the molecules are capable of producing a measurable response upon interacting with a compound which binds to the molecules. See paragraph 70. Such molecules can be nucleic acids or peptides and cells. See paragraph 228.

As to claim 4, Wigstrom et al. disclose using a microchannel (and thus its probes) as a control or standard. See paragraph 232.

As to claim 5, Wigstrom et al. disclose that the chips can be stacked to provide multi-dimensional microchannel networks. See paragraph 94. While Wigstrom et al.

teach that the device may be circular (see paragraphs 68 and 173) (it is understood that this means the device is cylindrical, since the device has three dimensions), Wigstrom et al. do not disclose that the chips are so stacked that the central axes of the columns or cylinders substantially coincide with each other. However, such stacking would have been obvious to one skilled in the art as centering elements, especially identically shaped elements, in such a manner is well understood to be a convenient means of stacking like elements.

As to claim 6, Wigstrom e al. do not teach a spacer arranged between adjacent two chips. However, Wigstrom et al. do teach interconnecting element(s) for interfacing the microfluidic substrate with a macroscale component, etc. See paragraph 68. While interconnecting element(s) for interfacing the individual microfluidic substrates (*chips*) are not disclosed, the skilled artisan would have recognized the same principle disclosed in paragraph 68 can be applied *between chips* for the same purpose, i.e., to interconnect chips through the interconnecting element(s) for interfacing the chips. Such interconnecting element(s) for interfacing the chips are equivalent to a spacer arranged between adjacent two chips.

As to claim 7, Applicant claims an incubator serving to bring a sample into contact with the biological chip wherein the incubator is so configured as to keep the central axis of the column(s) or cylinder(s) of the chip or chip assemblage substantially horizontal and to rotate the biological chip or chip assemblage around the central axis, and wherein the incubator is so configured as to immerse a vertically lower part of the chip or chip assemblage in a medium containing the sample.

It is noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the Wigstrom et al. system is capable of performing the intended use. Wigstrom et al. teach scanning of the substrate relative to one or more sensors (e.g., by moving the substrate, by moving the one or more sensors, or by moving both the substrate and one or more sensors). Movement may be in an x-, y-, and/or z-direction. Alternatively, or additionally, movement may comprise rotating and/or tilting the substrate and/or sensor. See paragraph 89. Motion along all axes can be driven by stepper motors so that precise and accurate positioning may be achieved. A servo motor or other actuator systems may be used for precise position control. See paragraph 173.

It is noted that the claims are interpreted to mean that the incubator must have the *capability* of bringing a sample into contact with the biological chip and the *capability* of keeping the central axis of the column(s) or cylinder(s) of the chip or chip assemblage substantially horizontal and rotating the biological chip or chip assemblage around the central axis, and the *capability* of immersing a vertically lower part of the chip or chip assemblage in a medium containing the sample, since the claim language refers to intended use The x-, y-, and/or z- movement capability of the Wigstrom et al. system is capable of performing these recited intended use/functions, because the Wigstrom et al. system can move the chip vertically and/or horizontally and/or rotate

the chip. It is noted that a medium containing the sample is not claimed as part of the incubator.

As to claim 8, the Wigstrom et al. sensor is equivalent to the claimed measuring section. The rotation of the sensor and/or substrate (chip) is disclosed in paragraph 89. It is not disclosed that the rotation of the measuring section is along the circumferential side wall of the column (chip) around the central axis of the column or cylinder. However, such rotation would have been within the skills of the ordinary artisan since the ordinary artisan would have recognized that various movements of the sensor relative to the substrate (chip) can be used to achieve the purpose of providing for sensing capabilities, as, suggested by Wigstrom et al., in paragraph 89. The ordinary artisan would have reasonable expectation of success because Wigstrom et al. teach that parts of the chip, including the sensor chamber, is made of optically transmissive material to facilitate the collection of optical data from the sensor. See paragraph 99.

As to claim 9, Applicant claims that the assay device is so configured as to carry out an assay while rotating the chip around the central axis of the column(s) or cylinder(s). The rotation of the chip has been discussed above in claim 8. This rotation can be performed during an assay (e.g., sensing step.)

As to claim 10, Wigstrom et al. disclose a cover layer of an optically transmissive material is bonded to the substrate (paragraph 99). Because the optically transmissive material is disclosed as being used to facilitate the collection of optical data from the sensor (paragraph 99), it is understood that the sensor may be placed on the other side of the cover layer during the assay detection step.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wigstrom et al. 20040181343, in view of Anderson et al., 7,179,638.

Wigstrom et al. has been discussed above. However, Wigstrom et al. do not teach that the chip further comprises an index mark indicating the position of the immobilized probe on the surface of the substrate (claim 2), or plural positions of the immobilized probes are separated into plural groups wherein the index marks are so arranged at predetermined positions on the substrate as to distinguish one group from another (claim 3).

However, Anderson et al. teach a device comprising a substrate and multiple discrete channels, the channels comprising a first and second binding reagent immobilized on the walls of a first and second group of channels. The binding reagents may or may not be identical. See column 3, lines 24-31. Anderson et al. also teach that any of the conventional binding assay formats involving an immobilized binding partner may be used. For example, the microarray cell may be labeled. The labels may be interacting with each other to make a detectable signal or product, or to quench a signal

or product. The number of different combinations is in the dozens and any may be used in the instant invention as well as different combinations for different cells of the microarray assay. See column 20, lines 23-36. The arrays can be used for testing chemical interactions and reactions, enabling testing different reactive chemicals simultaneously against a test substance or material. or one may assay for desirable interactions between the analyte and all of the molecules of interest in the array. See column 22, lines 5-14. The binding partners may be nucleic acids or cells or antigens or antibodies. Column 35, lines 35-49. To distinguish selected channels, one either may seal off the selected channels and/or fill the channels with an easily detectable substance. Different colored inks, dyes and colored materials are particularly well suited as well as detectable components similar to or opposite from the detectable component(s) being detected in other cells. Printing methods with drying inks or plastics, sublimation, solvent containing an ink, or ink-jet printing may be used. The indicia so formed permits better alignment or easily detectable marking when the array is in use. That permits easy optical alignment. See column 35, lines 24-34.

It would have been obvious to one of ordinary skills in the art at the time the invention was made to provide *different* binding partners immobilized on the Wigstrom et al. channels and to provide detectable substance in the channels as taught by Anderson et al. because Anderson et al. teach that utilizing different binding partners provides for the benefit of simultaneous assays, as would be desirable for convenience, and that providing different detectable substance in the channels allows for the benefit of distinguishing the channels, which may have reagents that are not

identical. Since it is disclosed that the detectable substance *fill* the channels, it is understood that the detectable substance are also on the surface of the substrate (i.e., the surface of the channel, wherein the channel is part of the substrate), which meets the limitations of claim 2. As to claim 3, the different channels with different immobilized molecules and different detectable substance, as suggested by Anderson et al., are equivalent to immobilized probes separated into plural groups, wherein the index marks are so arranged at predetermined positions on the substrate so as to distinguish one group from another.

Claims 11 -14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pourahmadi et al., 6,440,725, in view of Wigstrom et al. 20040181343.

Pourahmadi et al. disclose a cartridge incorporates microfluidic processing chips on various regions of the cartridge, which allows the entire processing facility to be small, yet capable of processing relatively large fluid samples and thus to take advantage of the unique properties of very small microfludiic chips or other fluid processing components. See column 5, lines 25-34.

The Pourahmadi et al. “cartridge” is equivalent to a chip since it is still relatively small. Put it another way, the Pourahmadi et al. “cartridge” is just a larger chip than the "chips” that are incorpoated into it. The Pourahmadi "chips” are equivalent to the claimed containers.

However, Pourahmadi et al. do not disclose that the cartridge is a columnar or cylindrical substrate, nor that the chips are arranged on the circumference of the substrate.

Wigstrom et al. disclose that a microfluidic chip typically comprises a plurality of microchannels through which picoliter-to-nanoliter volumes of solvent, sample, and reagents solutions progress through narrow tunnels to be mixed, separated, and/or analyzed. See paragraph 94. Wigstrom et al. also disclose that a “microfluidic substrate”, which refers to a substrate that comprises at least one microchannel, can be planar, but may be of any shape, including circular. The substrate may also have interconnecting element(s) for interfacing the microfluidic substrate with a macroscale component. See paragraph 68. Wigstrom et al. further disclose a "sensor chamber" which receives sensors and comprise outlets in one or more walls from at least two microchannels. The sensor chamber can for example be cylindrical (e.g., when the chamber is disc-shaped). One or more wall(s) and/or base can be optically transmissive. See paragraph 69.

It would have been obvious to the skilled artisan that the Pourahmadi et al. “chips” can be in any of various desired shape, including that of a cylinder as suggested by Wigstrom et al. It would have also been obvious to the skilled artisan to provide the Pourahmadi "chips" on the circumference of the cartridge since the skilled artisan would recognize that various arrangements of the chips on the cartridge can be provided as desired, and this is also suggested by Pourahmadi et al. in teaching that the “chips” can be arranged in various regions of the “cartridge. See column 5, lines 25-34.

As to claim 12, the Pourahmadi et al. “chips” are detachably arranged on the cartridge. See column 10, lines 62-67.

As to claims 13 and 14, the containers contain assay reagents, including dried (solid) reagents. See column 12, lines 11-13 and 34-37.

As to claim 17, Applicant recites that the containers carry identifying marks on their outer surfaces for distinguishing one container from another.

Wigstrom et al. teach providing a display interface that displays a screen on which various substrate properties are displayed. For example, the screen may provide a selectable menu on which different types of substrate configurations are indicated. The user interface may display a drop down menu with the label CHIP TYPE. A substrate type should be selected which is the same type as the substrate being used. In one aspect, a CHIP TYPE identifier indicated in the drop down menu corresponds to the number of microchannels provided in the chip. However, other identifiers can be used which can be associated with particular types of chip geometry by the application program. Similarly, a plurality of identifiers can be used to identify a substrate type. For example, a set of identifiers can designate the number of microchannels leading to a sensor chamber in the chip for receiving a sensor, as well as identifying the geometry of the microchannels (e.g., parallel, fish bone, spokes-wheel, and the like). Preferably, this is done each time an application is selected. In one aspect, the substrate is coded with a bar code, a radiofrequency tag, or other identifier that is recognized by the microfluidic system (e.g., by a detector, receiver, and

the like) and this triggers the user interface to display a display screen appropriate for the type of substrate. For example, upon recognizing a barcode, the system can display the numbers of channels, interchannel distances and other properties associated with the substrate identified by the barcode, the properties listed in a table comprised in a relational database which is part of the system. See paragraph 161.

It would have been obvious to the skilled artisan that this same principle of identifying a chip can be used to identify the chips in the Pourahmadi et al. invention in order to identify the chips as having a certain number of microchannels, or other types of characteristics of a chip as deemed desirable by the skilled artisan, as suggestegd by Wigstrom et al.

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pourahmadi et al., 6,440,725, in view of Wigstrom et al. 20040181343, and further in view of Mink et al., 6,303,081.

Pourahmadi et al. has been discussed above regarding claims 11 and 13. Additionally, Pourahmadi et al. teach that the desired analyte may comprise, e.g., organisms, cells, proteins, nucleic acid, carbohydrates, virus particles, bacterias, chemicals, or biochemicals. See column 5, lines 38-41.

However, Pourahmadi et al. do not teach that the analyte are one of the specifics listed in claim 15, such as cholesterol.

Mink et al. teach detection and/or quantification analyte, including markers of pathology such as cholesterol. Column 7, lines 46-56. The detection is based on binding or reacting with a binding partner using for example immunoassay formats well known in the art. See column 6, lines 35-52.

As to claim 16, Mink et al. also teach use of labels, such as fluorescent dyes and detection of such labels as is well known to those of skill in the art. See column 6, lines 53-67. The label is an additional, different assay reagent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN Y. LAM whose telephone number is (571)272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ann Y. Lam/
Primary Examiner, Art Unit 1641